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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/634,711 | 08/05/2003 | William F. McKay | 4002-3365 | 8938 |
| 7590 | 01/04/2005 | | EXAMINER | |
| Woodard, Emhardt, Moriarty, McNett & Henry LLP Bank One Center/Tower Suite 3700 111 Monument Circle Indianapolis, IN 46204-5137 | | | SNOW, BRUCE EDWARD | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |
| DATE MAILED: 01/04/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/634,711 | MCKAY, WILLIAM F. <i>CR</i> |
| Examiner | Art Unit | |
| Bruce E Snow | 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 November 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 3-8, 14, 17, 21-29, 34, 35 and 39-41 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 2, 9-11, 13, 15, 16, 18-20, 30-33, 36-38 and 42 is/are rejected.
- 7) Claim(s) 12 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/5/03</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 8/5/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The Examiner does not have the ability to obtain a copy of Minns, "Preliminary Design and Experimental Studies of the Novel Soft Implant..". **Please send a copy in response to this Office action. Additionally, please include a copy of Mays (EP 577179).**

Regarding DE 4409836 and WO 91/06266, neither was previously cited. See US 6,648,916 for previously cited prior art.

Election/Restrictions

Applicant's election without traverse of Species 17 (figure 37) in the reply filed on 11/29/04 is acknowledged.

Claims 3-8, 14, 17, 21-29, 34-35, 39-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species as indicated by applicant.

Allowable Subject Matter

Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 31 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all claims of U.S. Patent No. 6,146,420. Although the conflicting claims are not identical, they are not patentably distinct from each other both claiming an implant comprising opposite end pieces and a central element. It would have been obvious to one having ordinary skill in the art to include "a tool" for insertion of the implant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich (DE 19630256)

Ulrich teaches a spinal implant system comprising an implant having opposite end pieces having opposite surfaces configured to contact and support adjacent vertebrae; a longitudinally “central” element 19 connecting the end portions defining a pocket. A tool corresponding to hex element 11, etc. is inherent

Claims 1-2, 10, 15-16, 18-20, 30-32, 36-38, 42 are rejected under 35 U.S.C. 102(b,e) as being anticipated by Grosse et al (WO 97/23174).

Grosse et al teaches a spinal implant system comprising at least first and second load bearing members (see figures 4-5), said loading bearing members comprising opposite end pieces 5a, 5b having opposite surfaces configured to contact and support adjacent vertebrae; a longitudinally “central” element 6 connecting the end portions; and an osteogenic material 2 or 10 having a consistency so as to be retainable “about” (approximately) said central element. Note that the central element is less in height than elements 5 forming a pocket between the central element and adjacent vertebrae. Referring to figure 14, the end pieces are interpreted as being truncated having a flat side in comparison to the configured shown in figure 15. The flat side allows the implant to be more closely nested.

Regarding claim 18, the claim only claims “configured to be nested”.

Claim 19, the implants as shown in figures 4-5 are interpreted as being “nested” together in the same vertebrae space.

Regarding at least claim 20, “around” does no mean bone growth material completely surrounds the central body (central element of claim 1).

Regarding claim 31, “the tool”, see figures 6-13.

Regarding claim 42, nesting the implant does not mean the implants have to be in direct contact with each other, obviously forming a pocket between the two. Additionally, if the implant were positioned in direct contact, a pocket is formed as shown in figure 3, element 2.

Claims 1-2, 9-11, 13, 15-16, 18-20, 30-33, 36-38, 42 are rejected under 35 U.S.C. 102(b,e) as being anticipated by Grosse et al (WO 97/23174).

Referring to at least figure 13-14, Grosse et al teaches a spinal implant system comprising at least first and second load bearing members; see column 5, lines 46 et seq. teaching the nesting of two, said loading bearing members comprising opposite end pieces having opposite surfaces configured to contact and support adjacent vertebrae; a longitudinally "central" elements connecting the end portions; and an osteogenic material 40 including BMP having a consistency so as to be retainable "about" (approximately) said central elements. Note figure 14 showing a concave truncated surface.

Regarding claim 11 requiring a carrier, see at least column 4, lines 8 et seq.

Regarding at least claim 20, "around" does no mean bone growth material completely surrounds the central body (central element of claim 1).

Regarding claim 31, "the tool", see tool receiving element 32, the tool is inherent.

Regarding claim 42, nesting the implant does not mean the implants have to be in direct contact with each other, obviously forming a pocket between the two.

Additionally, if the implant were positioned in direct contact, a pocket 40 is formed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

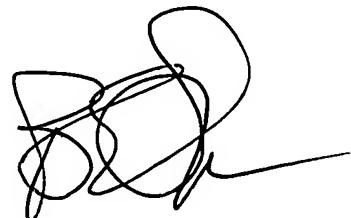
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes



A handwritten signature in black ink, appearing to read "BRUCE SNOW".

BRUCE SNOW
PRIMARY EXAMINER